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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,004	06/18/2003	Graham Edmund Kelly	7579.0015-01000	6037

22852 7590 06/17/2004

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EXAMINER
DELACROIX MUIRHEI, CYBILLE

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/600,004	KELLY ET AL.	
	Examiner	Art Unit	
	Cybille Delacroix-Muirheid	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-43 are presented for prosecution on the merits.

Information Disclosure Statement

Applicant's Information Disclosure Statements received Sep. 11, 2003 and Jan. 6, 2004 have been considered. Please refer to Applicant's copies of the 1449 submitted herewith.

Claim Objections

1. Claims 11, 13, 21, 40, 42 are objected to because of the following informalities: in claim 11, line 2, after "vitamin A", the "and" should be deleted and replaced with --or--. In claim 13, line 1, "incorporate" should read --incorporated--. In claim 21, line 7, before "daidzein", the "and" should be deleted and replaced with --or--. In claim 42, line 2, "treatment" should read --treating--. Finally, in claim 40, line 1, "39" should be cancelled and replaced --38--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. Claims 9, 12, 19, 20, 21, 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 9, 19, 21 the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Please see claim 9, page 30, line 1; claim 19, line 7; claim 21, line 4.

Regarding claim 12, the limitation "(0.5g to 2 g)" renders the claim indefinite because it is unclear whether the limitations within the parentheses are part of the claimed invention.

3. Claims 19-20 provide for the use of formononetin and one or more isoflavones, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 19-20 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

For purposes of this office action, claims 19-20 will be treated as a method of making a medicament.

4. Claim 25 recites the limitation "to reduce the risk of vascular disease" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelly WO 93/23069 in view of Empie et al., 6,261,565 B1 (both references already of record in parent file) and Kelly 6,340,703.

Kelly '069 discloses compositions enriched with phyto-estrogens selected from genistein, daidzein, formononetin and Biochanin A. These phyto-estrogens may be used as food additives or may be formulated into medicaments, i.e. tablets or capsules or powders, suspensions, or syrups, for promoting health in cases of cancer, pre-menstrual syndrome, menopause or hypercholesterolemia. Specifically, the compositions contain an excipient, diluent or carrier or may be mixed with food (drinks) or can be consumed directly. The phyto-estrogens may be obtained from red clover or subterranean clover or from soya. Other sources of the phytoestrogens include chick peas. Moreover, it is preferred that the ratio of genistein and/or Biochanin A to daidzein and/or formononetin is between 1:2 to 2:1. Finally, the compositions may be formulated along with vitamin supplements. Please see the abstract; page 8 to page 9, line 1; page 10, line 19; page 11, third full paragraph; page 13, last line to page 14, line 7. Kelly

additionally discloses that the compositions may be used to lower LDL thus leading to a reduced risk of developing atherosclerosis. Please see page 15, last full paragraph.

Kelly '069 does not specifically disclose using the compositions for treating osteoporosis or cardiovascular disease or vascular diseases or bone fractures; however, the Examiner refers to Empie et al., which disclose compositions prepared by extracting phytochemicals from soy or red clover, wherein the resulting composition comprises isoflavones consisting predominantly of genistein and/or Biochanin A and/or formononetin with a ratio of genistein to daidzein from 100:1 to 1:100. Please see the abstract; col. 4, lines 44-55. Empie et al. additionally disclose that isoflavones are known to be useful in treating osteoporosis, vascular effects, cardiovascular diseases including heart disease. Moreover, people who eat a diet high in soy show reduction of various symptoms discussed above, thus suggesting that ingesting a combination of these isoflavones at certain ratio such as that found in soy may result in an additive or synergistic effect. Please see col. 1, lines 39-43; col. 2, lines 25-53.

The Examiner also refers to Kelly '703, which discloses a method of treating osteoporosis by administering to a patient in need thereof a composition containing an effective amount (10:1 to 1:10) of formononetin and daidzein. Please see claims 6, 9, 14, 15.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods and compositions of Kelly '069 for use in treating osteoporosis, vascular disorders or cardiovascular disorders because in view of Empie et al. and Kelly's '703 disclosure, one of ordinary skill in the art would reasonably expect the substantially similar isoflavone containing compositions of Kelly to be effective in treating such disorders. Such a modification would have been motivated by

the reasonable expectation of producing a nutritional composition capable of effectively treating disorders already known to respond to treatment by administration of isoflavones.

Concerning the claims drawn to treating or preventing bone fracture, this would have been obvious from the methods of the prior art because one of ordinary skill in the art would reasonably expect that treatment of osteoporosis would serve to reduce the likelihood of bone fractures.

With respect to the addition of a calcium source, it would have been obvious to one of ordinary skill in the art to modify the compositions of Kelly and Empie to contain additional calcium with the reasonable expectation that the additional calcium would help to treat the patients suffering from osteoporosis as well as help repair bone fractures.

In addressing the specifically claimed vitamins, it would have been obvious to one of ordinary skill in the art to choose from a variety of known vitamins such that the overall composition is nutritionally balanced.

Finally, with respect to the claimed ratios, since Kelly '069 and '703 and Empie et al. have established that the therapeutic efficacy of the isoflavones is dependent upon their ratio amounts, it would have been obvious to one of ordinary skill in the art to further modify the methods and compositions of Kelly and Empie et al. such that the isoflavones are present in a ratio that is effective to optimize their therapeutic activity.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 9, 19-21, 28, 35 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6, 9, 14, 15 of U.S. Patent No. 6,340,703. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and USPN '703 claim a composition comprising a combination of formononetin and daidzein for use in treating osteoporosis. The composition contains a ratio of formononetin to daidzein, i.e. 15:1 to 2:1 (in the instant application) and 10:1 to 1:10 (in USPN '703).

The difference between the claims of the instant application and the claims of USPN '703 is that USPN '703 specifically claims a combination of two active agents, i.e. formononetin and daidzein, whereas the instant application claims a combination of two or more active agents, i.e. formononetin, daidzein, genistein and biochanin.

However, the scope of the claims of the instant application and the claims of USPN '703 overlap because at least two of the active agents (formononetin and daidzein) in the claimed compositions and methods are identical. Furthermore, the claimed ratios overlap and are obvious over another.

Conclusion

Claims 1-43 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is 571-272-0572. The examiner can normally be reached on Mon-Fri from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached at 571-272-0584. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM

June 8, 2004

Cybille Delacroix-Muirheid
Patent Examiner Group 1600